

REMARKS/ARGUMENTS

The foregoing amendments in the specification and claims are of formal nature, and do not add new matter.

Prior to the present amendment, Claims 28-40 were pending in this application and were rejected on various grounds. Claim 37 has been cancelled without prejudice. The rejection of the remaining claims is respectfully traversed.

Specification

The specification has been amended to remove embedded hyperlink and/or other form of browser-executable code.

Priority

According to the Office Action, "this application is supported by the disclosure in International Application Serial No. PCT/US00/04342, filed February 18, 2000 but is not supported by any of the earlier applications because no utility for the claimed polypeptide, PRO 1412, is disclosed in the earlier applications." Applicants rely on the chondrocyte re-differentiation assay (Example 153) for support of patentable utility. This data was first disclosed in International Application Serial No. PCT/US00/04342 filed on February 18, 2000, the priority of which is claimed in the present application.

Claim Rejections – 35 U.S.C. §112, Second Paragraph

Claims 28-33, 37, 39, and 40 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner noted that "[t]he limitation that the encoded protein comprises an 'extracellular domain' ... 'lacking its associated signal peptide' (Claim 28, part (d), for example) is indefinite[.]"

Since the term "extracellular domain ... lacking its associated signal peptide" is no longer present in Claims 28-33 (and, as a consequence, those claims dependent from the same), the rejection is believed to be moot, and should be withdrawn.

Claim 47 has been cancelled without prejudice and hence, the rejection to this claim is believed to be moot, and should be withdrawn.

Claim Rejections – 35 U.S.C. §112, First Paragraph

Claims 28-32, 39 and 40 are rejected under 35 U.S.C. §112, first paragraph, because "the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims."

Claims 28-32, 39 and 40 have been amended to recite polypeptides that are "capable of inducing chondrocyte redifferentiation." Since the claimed genus is now characterized by a combination of structural and functional features, any person of skill would know how to make and use the invention without undue experimentation based on the general knowledge in the art at the time the invention was made. As the M.P.E.P. states, "The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation" *In re Certain Limited-charge cell Culture Microcarriers*, 221 USPQ 1165, 1174 (Int'l Trade Comm'n 1983), *aff. sub nom., Massachusetts Institute of Technology v A.B. Fortia*, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985) M.P.E.P. 2164.01.

In addition, the Examiner has stated that the specification is "enabling for an isolated polypeptide having at least 80% amino acid sequence identity to the polypeptide of SEQ ID NO:140, which isolated polypeptide induces chondrocyte proliferation." (See Office Action, page 3). Accordingly, the Examiner is respectfully requested to reconsider and withdraw the present rejection.

Claim Rejections – 35 U.S.C. §112, First Paragraph

Claims 28-32, 39 and 40 are rejected under 35 U.S.C. §112, first paragraph, for alleged lack of sufficient written description. The Examiner noted that in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Claims 28-32, 39 and 40 have been amended to recite polypeptides that are "capable of inducing chondrocyte redifferentiation." This biological activity, coupled with a well defined, and relatively high degree of sequence identity is believed to sufficiently define the claimed genus, such that one skilled in the art would readily recognize that the Applicants were in the possession of the invention claimed at the effective filing date of this application. Hence, the present rejection should be withdrawn.

Claim Rejections – 35 U.S.C. §102

Claims 28-32, 39, and 40 are rejected under 35 U.S.C. §102(a) as being anticipated by International Patent Application Publication No. WO 00/00610 (Lal *et al.*, publication date January 6, 2000). Applicants respectfully submit the attached Declaration by Dr. Desnoyers, the consideration of which is respectfully requested.

Dr. Desnoyers, along with other inventors of the above-identified application, conceived and reduced to practice the invention claimed in the above-identified application in the United States prior to January 6, 2000.

The polypeptide designated as PRO1412 was first disclosed in the priority document, International Application Serial No. PCT/US99/20111 filed on September 1, 1999. The description of PRO1412 can be found at least on page 12 of the PCT publication. In addition, the amino acid sequence (SEQ ID NO: 140) and its encoding nucleic acid sequences (SEQ ID NO: 139) for PRO1412 can be found at least on page 302 under the description of Figures 83 and 84 and in the claims of the PCT publication.

For each PRO polypeptide, its encoding nucleic acid sequence is assigned to a DNA number and an UNQ Number. As indicated in the brief description of Figure 83 on page 302 of the PCT publication and on page 289 of the present specification, the assigned numbers for PRO1412 are DNA 64897-1628 and UNQ730.

The attached Exhibits A and B show the positive results obtained for PRO1412 polypeptide based on the chondrocyte proliferation assay. Chondrocyte proliferation assay is used to find agents that are capable of inducing chondrocyte proliferation and/or redifferentiation. The assay was performed on PRO1412 polypeptide following the protocol described in Example 153 of the specification. According to the protocol, isolated chondrocyte cells are seeded in 96 well plates with either serum-free medium (negative control), staurosporin (positive control) or the test PRO polypeptide. After 5 days, fluorescence dye is added to each plate and measured. The readout of the fluorescence from a plate containing the serum-free medium is measured to establish a background fluorescence level. A positive result in the assay is obtained when the fluorescence of the PRO polypeptide-treated sample is more like that of the positive control than the negative control. This type of fluorescence determination, wherein the readout is compared to positive and negative controls, is well known in the art.

The Genengenes database stores experimental data from the chondrocyte proliferation assay for each PRO polypeptide according to its UNQ number. The database additionally assigns a pin number (shown under "LOT Name") for each UNQ number. For PRO1412 polypeptide, the assigned pin number is PIN753-1.

A copy of a page from the Genengenes database displaying the positive results for PRO1412 polypeptide is shown as Exhibit A to the declaration.

Copies of pages from Dr. Desnoyers' laboratory notebook showing the positive results for PRO1412 from the assay are shown as Exhibit B. The positive results shown in Exhibit B for PRO1412 polypeptide, identified by its pin number PIN753-1, are indicated with an arrow.

All of the results shown in Exhibits A and B were obtained prior to January 6, 2000.


The Declaration clearly show that the invention claimed in the present application was conceived and reduced to practice prior to January 6, 2000. Accordingly, the Examiner is respectfully requested to reconsider and withdraw the present rejection.

The present application is believed to be in *prima facie* condition for allowance, and an early action to that effect is respectfully solicited.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 08-1641 (Attorney's Docket No. 39780-2830 P1C9). Please direct any calls in connection with this application to the undersigned at the number provided below.

Respectfully submitted,

Date: April 7, 2004

By: 
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